Arent Fox LLP Attorney Docket No. 029489.00023

## **Amendment of Claims:**

- 1. (Withdrawn) A process for the preparation of a pharmaceutical composition comprising an active pharmaceutical ingredient capable of existing in multiple polymorphic forms, comprising a step of preparation of a wet phase comprising said active pharmaceutical ingredient and microcrystalline cellulose and a liquid, wherein in said wet phase has a weight ratio of active pharmaceutical ingredient to microcrystalline cellulose above 1.0 or a weight ratio of active pharmaceutical ingredient to liquid above 1.0.
- 2. (Withdrawn) A process according to claim 1 wherein said wet phase is an alcoholic phase and in said wet phase the weight ratio of active pharmaceutical ingredient to microcrystalline cellulose is above 1.0 and the weight ratio of active pharmaceutical ingredient to alcoholic liquid is above 1.0.
- 3. (Withdrawn) A process according to claim 1 wherein said weight ratio of active pharmaceutical ingredient to the liquid is above 2.0.
- 4. (Withdrawn) A process according to claim 1 wherein said liquid is an alcoholic liquid consisting of only absolute ethanol or of an aqueous ethanol solution.
- 5. (Withdrawn) A process according to claim 1 wherein said microcrystalline

Arent Fox LLP Attorney Docket No. 029489.00023

cellulose is incorporated into the composition in more than one step.

- 6. (Withdrawn) A process according to claim 1 wherein the active pharmaceutical ingredient is pravastatin sodium.
- 7. (Withdrawn) A process according to claim 6 wherein the liquid is ethanol and the weight ratio of pravastatin sodium to microcrystalline cellulose is above 1.0 and the weight ratio of pravastatin sodium to ethanol is above 2.0.
- 8. (Withdrawn) A process according to claim 1 wherein the active pharmaceutical ingredient is crystalline pravastatin sodium having characteristic peaks in a X-ray diffractogram at 20 of 4, 10.2, 16.3, 17.3, and 20:0  $\pm$  0.2°.
- 9. (Withdrawn) A process according to claim 8 wherein the crystalline pravastatin sodium exhibits an X-ray diffraction pattern substantially similar to that in Figure 2 of US 6,740,775.
- 10. (Withdrawn) A process according to claim 6 whereby pravastatin sodium in a first polymorph form is stabilized against conversion into a polymorph form which exhibits broad peaks in X-ray diffraction pattern, having half-value widths of significant peaks above 2° 2 Theta.
- 11. (Withdrawn) A process according to claim 1 wherein a binder is incorporated into the composition in a step other than the step of preparation of an alcoholic phase.
- 12. (Withdrawn) A process according to claim 11 wherein said binder is

polyvinylpyrrolidone (PVP).

- 13. (Currently Amended) A pharmaceutical composition obtainable by the <u>a</u> process of claim 1 comprising preparing a wet phase comprising an active pharmaceutical ingredient, microcrystalline cellulose and a liquid, and then removing the liquid, wherein in at least the wet phase, the weight ratio of active pharmaceutical ingredient to microcrystalline cellulose is greater than 1.0 and/or the weight ratio of active pharmaceutical ingredient to liquid is greater than 1.0.
- 14. (Currently amended) A stabilized pharmaceutical composition comprising the a polymorph form of pravastatin sodium and microcrystalline cellulose in a ratio of pravastatin sodium to microcrystalline cellulose greater than one, wherein the greater than one ratio of pravastatin sodium to microcrystalline cellulose occurs at least in a wet phase, wherein the polymorph of pravastatin sodium which exhibits an X-Ray diffraction pattern with significant peaks having half-value widths below 2° 2 Theta characterized in that the polymorph form of pravastatin sodium and is stabilized against converting into one exhibiting peaks in an X-ray diffraction pattern, having half-value widths of significant peaks above 2° 2 Theta.
- 15. (Withdrawn) A method of using the pharmaceutical composition according to claim 13 for the manufacture of a medicament for the treatment of hypercholesterolemia.
- 16. (Withdrawn) A method of preventing or treating

Arent Fox LLP Attorney Docket No. 029489.00023

US Application No. 10/590,80 Inventor: Janez KERC

hypercholesterolemia in a susceptible patient, comprising administering to said patient a therapeutically effective amount of the pharmaceutical composition of claim 13.

- 17. (New) The pharmaceutical composition of claim 13, wherein the active pharmaceutical ingredient is a polymorph form of pravastatin sodium which exhibits X-Ray diffraction pattern with significant peaks having half-value widths below 2° 2 Theta, wherein the liquid is a C1-C4 alcohol and wherein the microcrystalline cellulose has an average particle size of from 10 to 200 microns and wherein the liquid is removed by drying.
- 18. (New) The pharmaceutical composition of claim 14, wherein the wet phase comprises alcohol and the ratio of pravastatin sodium to alcohol is greater than one.
- 19. (New) The pharmaceutical composition of claim 18, which has been dried and formulated into a capsule or tablet.
- 20. (New) The pharmaceutical composition of claim 13, which has been dried and formulated into a capsule or tablet.
- 21. (New) The pharmaceutical composition of either claim 13 or 14, wherein in at least the wet phase, the ratio of prevastatin sodium to microcrystalline cellulose is greater than 2.